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SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

As required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew HEALICOIL PK Suture Anchor

Date Prepared: November 7, 2011

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road, Andover, MA 01810

B. Company Contact

Elizabeth Lavelle
Senior Regulatory Affairs Specialist
Phone: (508) 261-3607

C. Device Name

Trade Name:	HEALICOIL PK Suture Anchor
Common Name:	Suture Anchor
Classification Name:	Fastener. fixation, non-degradable, soft tissue

D. Predicate Devices

The Smith & Nephew HEALICOIL PK Suture Anchor is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed device in commercial distribution: Smith & Nephew Next Generation Fully Threaded PK Suture Anchor (K110545).

E. Description of Device

The HEALICOIL PK Suture Anchor is manufactured from PEEK (polyetheretherketone) and is offered in diameters of 4.5mm and 5.5mm sizes. The screw-in anchor is pre-assembled onto a stainless steel inserter and pre-loaded with up to three strands of suture.

F. Intended Use

The Smith & Nephew HEALICOIL PK Suture Anchor is intended for use for the reattachment of soft tissue to bone for the following indications:

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Shoulder:
- Bankart lesion repairs
- Slap lesion repairs
- Capsular shift or capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps tenodesis

Knee:
Extra-capsular repairs:
- Medial collateral ligament
- Lateral collateral ligament
- Posterior oblique ligament

Patellar realignment and tendon repairs:
- Vastus medialis obliquous advancement

Iliotibial band tenodesis.

Foot & Ankle:
- Hallux valgus repairs
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstruction
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions

Elbow:
Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair
Biceps tendon reattachment

Hip: Gluteal tendon repairs
- Gluteus medius and gluteus minimus repair

G. Comparison of Technological Characteristics

The Smith & Nephew HEALICOIL PK Suture Anchor is substantially equivalent in design, materials, technological characteristics, intended use, and indications for use to its currently marketed predicate device, the Smith & Nephew Next Generation Fully Threaded PEEK Suture Anchor.

H. Summary Performance Data

There have been no design modifications that required additional mechanical testing. Performance characteristics of the anchors have not changed from those described in K110545.

The purpose of this submission was to update the labeling to include results from an animal study. The animal study evaluated bone growth into the HEALICOIL PK Suture Anchor and a control suture anchor via micro computed tomography (micro CT) and histology. The labeling updates are as follows:

(1) The open architecture of the HEALICOIL PK Suture Anchor allows for new bone to fill the fenestrations between threads and into the central channel.
HEALICOIL PK suture anchors (5.5 x 20mm) were implanted into 4.5 x 20mm sites created in ovine cancellous bone (n=12) of the medial distal femur and evaluated by micro-CT and histology analysis 12 weeks post implantation. Micro-CT and histology analysis demonstrated that new bone formed within the HEALICOIL PK suture anchor in the fenestrations between the threads and into the central channel in all specimens.
Note: Animal data is not necessarily indicative of human clinical outcomes. These results have not been demonstrated in humans having a variety of bone quality based on specific disease states such as osteoporosis. The effect of formation of new bone on pullout strength was not shown.

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(2) The Smith and Nephew HEALICOIL PK Suture Anchor contained 63% of the bone volume of control bone by 12 weeks post-implantation in sheep.

HEALICOIL PK suture anchors (5.5 x 20mm) were implanted into 4.5 x 20mm sites created in ovine cancellous bone of the medial distal femur and compared to control intact bone of the same anatomical site at 12 weeks post implantation. Micro-CT analysis of new bone formed within the HEALICOIL PK suture anchor demonstrated that 21.9% of the implant volume was new bone by 12 weeks post-implantation (n=12). Micro-CT analysis of a 4.5 x 20mm volume of control bone from the same anatomical site demonstrates that intact bone has an average bone volume of 34.5% (n=12).

Note: Animal data is not necessarily indicative of human clinical outcomes. These results have not been demonstrated in humans having a variety of bone quality based on specific disease states such as osteoporosis. The effect of formation of new bone on pullout strength was not shown.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew Incorporated
% Ms. Elizabeth Lavelle
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

JAN 2 0 2012

Re: K113294
Trade/Device Name: Smith & Nephew HealiCoil PK Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: January 5, 2012
Received: January 6, 2012

Dear Ms. Lavelle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

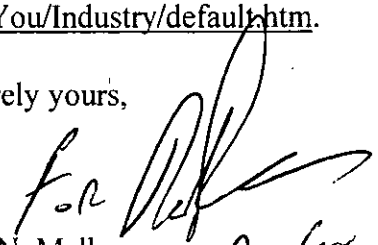
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113294

Device Name: HEALICOIL PK Suture Anchor (formerly Next Generation Fully Threaded Suture Anchor)

Indications For Use:

The HEALICOIL PK Suture Anchor (formerly Smith & Nephew Next Generation Fully Threaded PEEK Suture Anchor) is intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder:
- Bankart lesion repairs
- Slap lesion repairs
- Capsular shift or capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps tenodesis

Foot & Ankle:
- Hallux valgus repairs
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstruction
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions

Knee:
Extra-capsular repairs:
- Medial collateral ligament
- Lateral collateral ligament
- Posterior oblique ligament

Patellar realignment and tendon repairs:
- Vastus medialis obliquous advancement

Iliotibial band tenodesis.

Elbow:
Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair
Biceps tendon reattachment

Hip: Gluteal tendon repairs
- Gluteus medius and gluteus minimus repair

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for **(Division Sign-Off)**
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113294